Domperidone Use and Misuse in Parkinson Disease (DUMP)

First published: 29/10/2018

Last updated: 02/04/2024

Study Planned

Administrative details

EU PAS number

EUPAS26319

Study ID

33284

DARWIN EU® study

No

Study countries

☐ France

Study description

Parkinson disease (PD) is the second neurodegenerative disease affecting 1% of the population over 60 years (160000 patients in France), with treatment based on dopamine replacement therapies. Nausea is the most frequent adverse

event, occurring in 30-40% of patients at the treatment initiation whatever the drug. Because it does not cross the blood-brain barrier, domperidone, an antiemetic D2 receptor antagonist, is widely used in PD. Increasing risk of arrhythmia, sudden death and cardiac arrest reported with prolonged use and high doses, led the PRAC to recommend restricting domperidone use to patients younger than 60 years at doses below 30 mg/day and for 7 days maximum.The aim of this project is to conduct a pharmacoepidemiological study to determine the use and misuse of domperidone in PD in France based on complementary approaches: - A retrospective analysis of the French health insurance database (SNDS),- A cross sectional observational study performed in consecutive patients followed by the 24 PD expert centers of the NS Park network, general hospitals and private practice neurologists, - A qualitative approach to investigate the practices and beliefs of French neurologists regarding use and misuse of domperidone in PD.The first study will provide national patterns of domperidone dispensing to PD patients, the second will provide data on the actual use of domperidone by French neurologists and survey on regular practices of domperidone prescribing will provide information on the current opinions about the drug, the indications for which it is prescribed and how contra-indications are evaluated. This information will help Regulatory Authorities to communicate about the safety profile of the drug. Finally, our results obtained in the French population will be compared to those from the European Union countries using domperidone and from which data has been published.

Study status

Planned

Research institutions and networks

Institutions

University Toulouse III

France

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution

INSERM 1027

Centre de pharmaco-épidémiologie (Paris Pharmacoepidemiology Centre), Assistance Publique, Hôpitaux de Paris

France

First published: 14/11/2011

Last updated: 22/07/2015

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Pharmacologie En Population cohorteS biobanqueS (PEPSS), Hopitaux de Toulouse

France

First published: 31/03/2022

Last updated: 01/07/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Networks

RECAP

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Maryse Lapeyre-Mestre

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 02/01/2017

Actual: 02/01/2017

Study start date
Planned: 01/01/2018

Data analysis start date
Planned: 04/06/2018

Date of final study report
Planned: 06/01/2020

Sources of funding

- Other

More details on funding

Appel d'offres ANSM 2016

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

http://recap-inserm.fr/dump-fr.html

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Other

If ‘other’, further details on the scope of the study

Impact of safety recommendations

Main study objective:

The overall objective of this project will be to evaluate the conditions of domperidone use and misuse in PD patients in France.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

3 studies: repeated cross-sectional studies, prospective cohort, practice survey

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

DOMPERIDONE

Medical condition to be studied

Parkinson's disease

Population studied

Age groups

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

150000

Study design details

Outcomes

Misuse of domperidone defined as - Maximum daily dose > 30 mg - Maximum duration of prescription > 7 days - Age of patient > 60 years old- Contraindicated drug-drug interactions

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Data analysis plan

A description of the main characteristics of the PD population will be done: age, gender, comorbidities (using categories of the Charlson’s score), duration of follow-up, deaths during the follow-up. Characteristics of PD treatment (type of drugs, mono or poly therapy) and other drugs (main ATC Classes) will be investigated. Co-medications, specifically those potentially interacting with domperidone (pharmacodynamics or pharmacokinetic interaction) will be displayed, as well as drugs with similar indications than domperidone (other dopamine antagonists, setrons, apepritant…). Prevalence of misuse will be assessed as a whole in the PD population stratified on age, and for each category of misuse

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

04_AAP_ANSM_DPI_2016_declaration_interets_M Lapeyre-Mestre.doc.pdf(136.94 KB)

Composition of steering group and observers

Steering Committee DUMP.pdf(720.21 KB)

Signed code of conduct

Annex3_Declaration DUMP.pdf(183.66 KB)

Signed code of conduct checklist

Annex2_Checklist DUMP Seal.pdf(183.96 KB)

Signed checklist for study protocols

ENCePPChecklistforStudyProtocolsDUMP.pdf(270.79 KB)

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Other

Data sources (types), other

Prospective patient-based data collection, Survey among French neurologists about knowledge and beliefs regarding use, misuse and safety of domperidone in Parkinson disease

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No